

Remarks*35 U.S.C. § 102*

Claims 1, 2, 4-10, and 18-24 were rejected as being anticipated by Lipari (U.S. Patent No. 4,383,992). Anticipation requires that "each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." MPEP 2131, citing *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The claims have been amended so that unmodified  $\beta$ -cyclodextrin is not included. Rather a list of cyclodextrins derivatives is included. Since Lipari does not teach any of those cyclodextrin derivatives, it does not anticipate the claims as amended.

*35 U.S.C. § 103*

No prima facie case of obviousness has been made, nor indeed can be made, for the claims as now amended. MPEP 2143 states that "the prior art reference (or references when combined) must teach or suggest all the claim limitations." The prior art references cited in the Office Action do not teach or suggest all the claim limitations. Thus, no prima facie case of obviousness exists.

In the Office Action, Examiner alleges that delivery of a therapeutically effective amount of a drug to the back of the eye is inherent, observing "merely discovering and claiming a new benefit of an old process cannot render the process again patentable." This suggestion of inherency is incorrect.

To serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." MPEP 2101.01 (III) citing *Continental Can Co. USA v. Monsanto Co.*, 948 F.2d 1264, 1268, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991) (Emphasis added)

The references are silent about back of the eye delivery. Thus, Examiner must use extrinsic evidence to "make [it] clear that the missing descriptive matter is necessarily present in the thing described in the reference." Examiner has provided no extrinsic evidence or shown that the missing descriptive matter is necessarily present. In fact, the evidence of record suggests that the presently claimed method is not inherent. Delivery of a therapeutically effective amount to the back of the eye requires a significantly higher

concentration of a drug than delivery to the front requires. In the present application, administration of compositions with a prednisolone acetate concentration of around 0.5% to 1% topically resulted in prednisolone concentrations of around 400-800 ng/mL in the aqueous humor. This is about a 10,000 fold reduction in concentration. Furthermore, concentrations of prednisolone were further reduced to around 0-10 ng/mL in the vitreous humor, which is a 50-100+ fold reduction. Clearly, the concentration of drug delivered drops dramatically in going from the ocular surface, through the front of the eye, and toward the back of the eye. Thus, a composition intended for use in the front of the eye would not necessarily deliver a therapeutically effective amount of a drug to the back of the eye. Therefore, the method is not inherent in the prior art.

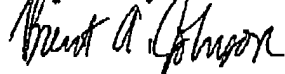
If back of the eye delivery is not inherent in the cited references, the cited references must explicitly teach or suggest back of the eye delivery for a prima facie case of obviousness to be made. Examiner has not shown how Loftsson teaches or suggests back of the eye delivery. Neither has Examiner shown how Lipari teaches or suggests back of the eye delivery. Thus, a prima facie case of obviousness has not been made, and the rejection does not properly apply to the claims as they now stand

In light of the amendments and the arguments made herein. Applicants believe that the claims are patentable as they now stand, and respectfully request that Examiner remove the rejections and allow the application to pass to issue.

Please use Deposit Account 01-0885 for extension of time fees or any other fees or credits relating to this response.

3/1/06

Respectfully submitted,



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